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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,700	09/24/1999	KARL-HERMANN SCHLINGENSIEPEN	P63763US0	5460

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400 SEVENTH STREET NW
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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01/15/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/341,700

Applicant(s)

SCHLINGENSIEPEN ET AL.

Examiner

Jane Zara

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may be considered untimely for earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 35-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

Art Unit: 1635

DETAILED ACTION

This Office action is responsive to the communications filed June 11, 2001, and October 30, 2001, Paper Nos. 19 and 22 respectively.

Claims 35-51 are pending in the instant application.

Election/Restriction

Applicant's election with traverse of SEQ ID No: 1754 in Paper No. 22 is acknowledged. The traversal is on the ground(s) that the required restriction to SEQ ID NO: 1754 is applicable to claim 47.

In accordance with the election of SEQ ID NO: 1754, claim 47 has been examined as being drawn to SEQ ID No: 1754. Claims 35-46 and 48-51 have been examined on their merits and are not restricted to SEQ ID No: 1754, however, as indicated in the Office action below.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 43 is objected to because of the following informalities: "sand" in line 1 of claim 43 should be changed to --and--. Appropriate correction is required.

Response to Arguments and Amendments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1635

Withdrawn Rejections

Rejection of claims 7, 13, 16 and 17 under 35 U.S.C. 112, second paragraph, is withdrawn in light of Applicants' amendments filed June 11, 2001, Paper No. 19.

Rejection of claims 14-17 under 35 U.S.C. 112, first paragraph, is withdrawn in light of Applicants' amendments filed June 11, 2001, Paper No. 19.

Rejection of claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over the combination of Milner et al and James in view of the combination of Vaerman et al and Ehrlich et al is withdrawn in light of Applicants' amendments filed June 11, 2001, Paper No. 19.

Rejections Necessitated by Amendments

Claims 35-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" needs to be defined in the claims.

The term "if necessary" in line 3 of claim 35 renders the claim vague and indefinite (i.e. Does this term refer to target nucleic acids whose sequences have not yet been delineated, or will the method work for target gene inhibition in the absence of such knowledge?).

Claims 50 and 51 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

Art Unit: 1635

example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 49-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of gene expression *in vitro*, does not reasonably provide enablement for *in vivo* gene inhibition and treatment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the reasons set forth in the prior Office action mailed August 28, 2000, Paper No. 14.

Applicant's arguments filed June 11, 2001 have been fully considered but they are not persuasive. Applicants argue that, in contrast to the *in vivo* problems encountered in the field of gene therapy using viral vectors or plasmid liposome complexes for gene delivery in organisms, *in vivo* antisense delivery and therapy is less unpredictable and is therefore enabled in the instant application because a person skilled in the art is aware of treatment conditions and modes of delivery of antisense oligonucleotides to organisms. Contrary to Applicants' assertions, the *in vivo* targeting and delivery of antisense oligonucleotides, and further whereby treatment or medicinal effects are provided in an organism, is still highly unpredictable for antisense oligonucleotides. Formulations and delivery protocols which allow for appropriate target cell delivery and target gene inhibition require undue experimentation beyond that which has been provided in the instant application.

Art Unit: 1635

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 35-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Crooke.

Crooke teaches methods for the preparation of antisense oligonucleotides comprising at least 8 residues, a maximum of twelve elements which are capable of forming 3 hydrogen bonds to cytosine bases, but does not contain 4 or more consecutive elements, does not contain 2 or more series of 3 consecutive elements, comprises a ratio of 3H bond forming elements to total nucleotides between 0.33 and 0.86, optionally comprises internucleotide, sugar and/or nucleobase modifications for enhancing stability against nucleases, and optionally comprises covalently linked hormones, peptides or phospholipids (See entire document, especially table 3 on page 335; last two paragraphs on page 335-first two paragraphs on page 337; compounds 1787, 1788, 1795 and 1796 in table 4 on page 345; first full paragraph on page 346; and first three full paragraphs on page 361).

Art Unit: 1635

Claims 35-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Baraccini et al.

Baraccini et al teach methods for the preparation of antisense oligonucleotides comprising at least 8 residues, a maximum of twelve elements which are capable of forming 3 hydrogen bonds to cytosine bases, but does not contain 4 or more consecutive elements, does not contain 2 or more series of 3 consecutive elements, comprises a ratio of 3H bond forming elements to total nucleotides between 0.33 and 0.86, optionally comprises internucleotide, sugar and/or nucleobase modifications for enhancing stability against nucleases, and optionally comprises covalently linked hormones, peptides or phospholipids (See entire document, especially col. 6-9; SEQ ID Nos: 16 and 20).

Allowable Subject Matter

Claim 47, drawn to SEQ ID No: 1754, is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1635

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ

January 10, 2002


ANDREW WANG
PRIMARY EXAMINER